

REMARKS/ARGUMENTS

Claims 18-20, 25-42 and 51-58 are pending in the application. Claims 18, 38 and 42 are independent.

Claim 18 has been amended. Support for the amendment is found throughout the specification. No new matter is added. Applicant respectfully submits that this amendment merely restate the claim and does not change the scope of the claim in any manner. For this reason, it is respectfully submitted that the subject amendment should not narrow the available scope of equivalents under the Doctrine of Equivalents.

Claims 29 and 32 are also amended. Support for the amendments can be found throughout the specification. No new matter is added. Applicant respectfully submits that the amendments broaden, not narrow, the scope of the claims. For this reason, it is respectfully submitted that the subject amendment should not narrow the available scope of equivalents under the Doctrine of Equivalents.

Reconsideration and favorable action are respectfully requested.

I. Claim Rejections - 35 USC § 112

1. Claim 29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe the mechanical piston at least partially disposed within the reservoir and advancing the mechanical piston into the reservoir.

Applicant respectfully traverses the rejection.

The claims are well supported in the specification. See for example, paragraphs [0051] on page 17, [0053] on page 18 and [0055] on page 19, reproduced below:

“[0051]The inventive compositions are preferably disposed in a delivery device 10 (e.g., FIGS. 2-4), such as a dispensing tube, pencil, pen or liquid stick having an applicator 12, such as a felt tip 14 (FIG. 3), brush 16 (FIG. 4), roller ball 17 (FIG. 10), or non-woven pad. In one embodiment, the delivery device 10 includes more than one applicator 12 that may be removably engaged with the device 10. In an embodiment wherein the device 10 is a pen or a pencil, the applicator 12 may be retractable and/or housed in a cap 18. The therapeutic dental composition L of the present invention may be housed directly within a reservoir 20 in the device 10 or may be supplied in a removable cartridge (not shown) within the reservoir 20 that may be replaced or refilled. The delivery device 10 may dispense the therapeutic dental composition through a transfer channel 21 through capillary action, such as in a flow through pen, or through an activator 22, such as mechanical piston 30, as shown in FIG. 9, with a click mechanism, twist button and ratchet mechanism, or push button mechanism, or through a vacuum method of ejection, or through other such mechanical means for transferring the composition from the device to an oral cavity surface in need of treatment. The activator 22 may be present on first end 24 of the device 10 and the applicator on a second end 26 of the device 10 or the activator 22 may be present on a side wall 28 of the device. In one embodiment, the delivery device 10 includes a felt tip 14 or brush 16 applicator 12 wherein the inventive composition is dispensed to the applicator 12 through actuation of the activator 22, such as by a clicking or twisting mechanism. Kotobuki Company, Japan, is one manufacturer of such types of delivery devices 10.

[0053] Upon applying external pressure to the activator 22 to expel the composition from the reservoir 20, the dental composition responds to shear forces introduced by the external pressure, and is temporarily reduced in viscosity to allow for ease of movement of the composition from the reservoir 20 through the transfer channel 21 to the applicator 12. Once the composition is positioned on the applicator 12, the user applies the composition to the teeth or gum surfaces, using the applicator 12 to apply and distribute the composition on the teeth and/or gums. Optionally, a set of instructions may be provided to the user in order that a particular application method or protocol be employed to apply the composition from the device 10 onto the teeth and/or gums in order to optimize the performance of the composition. With a twist mechanism, the user twists the activator 22 on the first end 24 of the delivery device 10 and the therapeutic dental composition L travels from the reservoir 20 through the transfer channel 21 to the applicator 12 at the other end. With the push button activator 22, the therapeutic dental composition L is delivered to the oral cavity surface with the push of a button activator 22 on the first end 24 or side wall 28, which transfers the composition from the reservoir 20 through the transfer channel 21 to the applicator 12.

[0055] The dental gel composition can be dispensed from any suitable delivery device 10 as described above. For example, the dental composition may be dispensed as a liquid or thin gel from a push button or twist actuated pen with an advancing piston mechanism 30 that expels a predetermined amount of liquid or gel through an orifice.

The pen delivery device 10 just described may also optionally comprise a set of bristles, advantageously positioned near or around the orifice through which the therapeutic dental liquid or gel is expelled. Expelling the therapeutic liquid or gel through the orifice and onto said bristles, the user may apply the therapeutic composition directly

onto the teeth, thereby forming a thickened gel upon application. Alternatively, the dental composition may be brushed onto an oral cavity surface, using a brush (FIG. 4) or felt tip (FIG. 3) that is replenished with the therapeutic composition by returning it to a reservoir containing said composition or by clicking or twisting a dispensing portion of the reservoir. Yet another mode of application is placement of the inventive therapeutic liquid or gel composition into a dental tray, whereupon the dental tray is inserted into place around a patient's teeth. Plastic strips may also be coated with a predetermined dose of the therapeutic responsive dental gel and placed against the teeth or gums of a subject. Alternatively, the inventive compositions may be applied by placing an amount on a swab or other such device, and simply applying directly to the intended oral cavity surface."

The mechanical piston is fully described with regard to the mechanism and the reservoir.

The exact words "a mechanical piston at least partially disposed within the reservoir" may not be there, but the description clearly supports the phrase. Also, Applicant has amended claim 29 to broaden the scope. The rejection is now moot.

As for claim 32, the specification, including that cited above, and especially the wording "an advancing piston mechanism 30 that expels a predetermined amount of liquid or gel" clearly describe what is in claim 32. Also, claim 32 is being amended to broaden the scope. The rejection is therefore moot.

Reconsideration is respectfully requested.

II. Claim Rejections - 35 USC §102

1. Claims 18, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Green (5,829,976). Green discloses a therapeutic dental delivery device comprising a liquid oral therapeutic dental composition (column 1 line 67), an applicator of a brush (column 1 line 14), an activator 32 coupled to the applicator of a push button mechanism and a reservoir 30 located between the applicator and configured to store the composition, a cap 14 having an open end terminating at a position between the activator and the applicator, the activator is configured to dispense the composition from the reservoir to the applicator. The Examiner concludes that the intended use of the composition outside of the delivery device does not impose any further structural limitation on the device and is given little patentable weight, the composition is capable of increasing viscosity such as through drying in the environment, moist or dry.

Applicant respectfully traverses the rejection.

Green discloses "a disposable fibrous dental applicator tip that is fed medicament via a cannula from the body or base of the instrument. In Green, the tip includes a flexible cannula core which is completely covered with a nonwoven, tufted surface which is capable of removing plaque. The fibrous applicator tip is specifically designed to massage the interproximal root surfaces and simultaneously deliver medication directed at the sources of periodontal diseases, such as bacteria and endotoxins in the gingival sulcus between the teeth." See col. 1, lines 53-62. (Emphasis added). "The design of the tip for penetration and scrub as well as the delivery of medication makes the device highly effective in removing plaque and neutralizing endotoxins and collagenases found in the periodontal pocket." See col. 2, lines 21-24. (Emphasis added). "A finger pump 32 is incorporated into the applicator base 12 to

allow the user to apply pressure from any compressible fluid to the reservoir and force the medicament from the reservoir into the tip of the instrument. In one embodiment, finger pump 32 pressurizes air in an air bladder 34 and the compressed air is forced into the space 36 between the casing 29 and the reservoir wall 38. One-way valves 40 and 42 maintain the air pressure generated by the finger pump 32 so that the reservoir wall gradually collapses and forces the medicament through the cannula and into the tip of the instrument." See col. 4, lines 9-19. (Emphasis added)

Claim 18, as amended, recites, in relevant parts "a liquid oral therapeutic dental composition, said therapeutic dental composition comprises a moisture or temperature responsive composition that increases in viscosity in a more humid environment;

an applicator for applying the composition to the oral cavity, is selected from the group consisting of a brush, felt tip or a roller ball;

an activator coupled to the applicator, said activator is selected from the group consisting of a push button click mechanism and a twist and ratchet mechanism; ..."
(Emphasis added).

Applicant disagrees with the Examiner's statement that the intended use of the composition outside of the delivery device does not impose any further structural limitation on the device and is given little patentable weight, and that the composition is capable of increasing viscosity such as through drying in the environment, moist or dry.

First, Applicant respectfully submits that the phrase "increases in viscosity in a more humid environment" describes the property of the composition in the applicator, and is not related to any intended use. Any composition without that property is not going to possess or develop such a property on its own and only a composition with

such a property is going to increase viscosity because it is in a more humid environment. Also, it is not true that there is drying in the environment, moist or dry. If such were the case, one would not get wet in a rainstorm.

Second, while it is true that a composition is capable of increasing viscosity such as through drying, Applicant respectfully submits that it is counterintuitive for a composition to increase in viscosity in a moist environment. For this reason, the present invention is inventive.

Third, Applicant respectfully notes that the Examiner admits that Green does not explicitly show the composition that increases in viscosity in a moist environment in her 35 USC § 103 rejections illustrated below.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d. 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d. 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. § 102(b).

Applicant respectfully submits that Green does not teach or motivate every element of the invention of claim 18, for the reasons noted above. Therefore, claim 18 is patentable over Green.

Claims 25 and 27 are dependent from claim 18 and are also rejected under 35 U.S.C. 102(b) as being unpatentable over Green. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that their

rejections are moot in view of the remarks made in connection with independent claim 18. The dependent claims include all of the limitation of the base claim and any intervening claims, and recite additional features which further distinguish the claims from the cited references. Therefore, claims 25 and 27 are also patentable under 35 U.S.C. 102(b) over Green.

Applicant respectfully requests that the rejection of claims 18, 25, and 27 under § 102(b) as being anticipated by Green be withdrawn. Reconsideration is respectfully requested.

III. Claim Rejections - 35 USC § 103

1. Claim 18-20, 25, 27, 33, and 38 are rejected, in the alternative under 35 U.S.C. 103(a) as obvious over Green in view of Ding et al. (6,541,020). Green discloses the therapeutic dental delivery device that shows the limitations as described above and the composition stored in the reservoir of the device is capable of its intended use; however, Green does not explicitly show the composition that increases in viscosity in a moist environment. Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel (moisture or temperature responsive) composition that increase in viscosity. The Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Green in order to have a composition that can be easily dispensed and provide controlled release of therapeutic agent in view of Ding et al. Ding et al. show the composition comprising a moisture responsive gel carrier and a therapeutic agent, and it would have been obvious matter of choice to have a compound in salt form in the

composition. The gel carrier comprises polymer complex comprising carboxypolymethylene and polyvinylpyrrolidone (column 13, line 56, 60).

Applicant respectfully traverses this rejection.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Applicant agrees with the Examiner that Green does not explicitly show the composition that increases in viscosity in a moist environment.

Ding et al disclose "carrier hydrogel compositions of the invention are compositions comprising a polymer material that forms a hydrogel at physiological temperatures and a polypeptide which is either T20 or T1249. The carrier hydrogel compositions of the invention are ideally suited for administering the specific peptides, referred to as T20 and T1249, which are described herein, as well as derivatives of the T20 and T1249 peptides described herein." See Col. 2, Line 54-64. "The carrier hydrogel compositions comprise gelling materials that possess a reverse thermal gelation property, and at least one peptide, i.e., T20, T1249 or a derivative thereof. The carrier hydrogel compositions exist as liquid, aqueous solutions at temperatures that are below physiological temperatures. However, when the gelling materials are exposed to physiological temperatures (e.g., temperatures of about 37.degree. C.) they form a polymer gel which is biodegradable or at least bioerodible. Such carrier hydrogel compositions can be stored indefinitely in an aqueous state. The carrier hydrogel

composition can then be administered to a patient in liquid form, e.g., by subcutaneous injection. Upon administration, the carrier hydrogel composition is heated to the patient's body temperature and forms a polymer gel which then acts as a sustained-release matrix for the peptides." See Col. 2, Line 65 to Col.3, Line 14. "Aqueous solutions of these polymers form micelles (microscopic spheres incorporating water) at low concentrations, and turn into thick continuous gels at higher concentrations (e.g., approximately 20-30% by weight) and elevated temperature (e.g., approximately 30.degree. C.)" (Emphasis added). See Col. 6, Line 35-40. While Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel, they do not teach a composition that increases in viscosity in a more humid environment, as the concentration of the polymer in a more humid environment is lower. Therefore, Ding et al actually teach away from the present invention and claim 18 is patentable over Green (5,829,976) in view of Ding et al. (6,541,020).

Applicant respectfully submits that Ding et al. also do not suggest or teach the invention of claim 38, which recites, in relevant parts, "a liquid oral therapeutic dental composition comprising a moisture responsive gel carrier and...the gel carrier comprises a polymer complex including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt" (Emphasis added), as noted above. Since Ding et al. do not supply the deficiency of Green, Green in view of Ding et al. do not establish a *prima facie* case of obviousness, as set forth in MPEP §2142. Therefore, claim 38 is also patentable over Green (5,829,976) in view of Ding et al. (6,541,020).

Claims 19, 20, 25, 27, and 33 are dependent from claims 18 and 38 are also rejected under 35 U.S.C. 103(a) as obvious over Green in view of Ding et al. While Applicant does not acquiesce with the particular rejections to these dependent claims, it

is believed that this rejection is moot in view of the remarks made in connection with independent claim 18 above. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish them from the cited references. Therefore, dependent claims 19, 20, 25, 27 and 33 are also in condition for allowance.

Applicant respectfully requests that the rejection of claims 18-20, 25, 27, 33 and 38 under 35 U.S.C. 103(a) as being unpatentable over Green (5,829,976) in view of Ding et al. (6,541,020) be withdrawn. Reconsideration is respectfully requested.

2. Claims 18-20, 26, 28-30, 32, 33, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace (1,362,937) in view of Marx et al. (1,041,315) and further in view of Ding et al. Grace discloses the therapeutic dental delivery device comprising a dental composition (page 2 line 50), an applicator 30 of a brush, an activator coupled to the applicator of a twist mechanism and a reservoir 26 located between the applicator and the activator and configured to store the composition, the activator is configured to dispense the composition from the reservoir to the applicator; however, Grace does not show a cap. Marx teaches a dental device comprising a cap for covering the applicator having an open end. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the device with the cap of Marx in order to protect the brush from dust and impurities in view of Marx. It would have been obvious to one of ordinary skill in the art made as to the specific activator, since interchanging of twist mechanism in the device with a push button involves only routine skill in the art and Grace suggests other mechanical embodiments.

The Examiner further notes that the modified device does not show composition that increases in viscosity in a moist environment. Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel (moisture or temperature responsive) composition that increase in viscosity. It would have been obvious to one having ordinary skill in the art that increase in viscosity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Grace and Marx in order to have a composition that can be easily dispensed and provide controlled release of therapeutic agent in view of Ding et al. Ding et al. show the composition comprising a moisture responsive gel carrier and a therapeutic agent, and it would have been obvious matter of choice to have a compound in salt form in the composition. The gel carrier comprises polymer complex comprising carboxypolymethylene and polyvinylpyrrolidone (column 13, line 56, 60).

Applicant respectfully traverses the rejection.

Grace discloses a fountain brush having a reservoir for receiving a replaceable refill cartridge 26 containing plastic or other material to be delivered to the bristles through a hollow shank by extrusion. See page 1, lines 11-19. A plunger has a plunger head 33 which is tapered to be pressed against the walls of the cartridge 26, and a plunger rod 34 having external threads for screwing the plunger rod 34 into the cartridge 26. (Emphasis added). See pages 2-3. "The plunger rod 34 is slotted longitudinally at its rear end ... whereby the rear end of the plunger is resilient so that the front end may be placed against a table ... so that pressure exerted forwardly on the cap 40 will cause the threaded feed barrel 39 to slip over the threads 37, thereby giving a quick turn of the plunger rod 34 to the rear position for another operation." (Emphasis added). See page 2, lines 113-125. Grace also discloses that "the threads 37, 28 in practice

have a pitch such that one turn of the cap 40 will cause a sufficient quantity of the paste or the like to be extruded to answer for a single service" (page 2, column 2, line 126 to page 3, column 1, line 1). Thus, not only does Grace not show a cap, as admitted by the Examiner, but Grace also does not disclose a liquid oral therapeutic dental composition, said therapeutic dental composition comprises a moisture or temperature responsive composition that increases in viscosity in a more humid environment (Emphasis added), or an activator such as a push button click mechanism or a twist and ratchet mechanism, etc.

Marx discloses a protective cover for a tooth brush. Since Marx is only cited by the Examiner to teach a cap for covering the applicator, the deficiencies in Grace are not supplied by Marx, for the reasons noted above.

The Examiner further cited Ding et al. to show composition that increases in viscosity in a moist environment. As noted above, while Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel, Ding et al. do not teach a composition that increases in viscosity in a more humid environment, as the concentration of the polymer in a more humid environment is lower. Since the deficiency in Grace is not supply by either Marx or Ding et al., Grace in view of Marx and further in view of Ding et al. does not establish a *prima facie* case of obviousness, as set forth in MPEP §2142. Therefore, claim 18 is patentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020).

Similar to the invention of claim 18, Applicant respectfully notes that Grace in view of Marx and further in view of Ding et al. does not teach the invention of claim 38, which recites, in relevant parts, "a liquid oral therapeutic dental composition comprising a moisture responsive gel carrier and...the gel carrier comprises a polymer

complex including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt" (Emphasis added). As admitted by the Examiner, the modified device (Grace in view of Marx) does not show composition that increases in viscosity in a moist environment (Emphasis added), namely, Grace in view of Marx does not show a moisture responsive composition. Furthermore, as illustrated above, Ding et al. do not supply the deficiency of Grace in view of Marx, and thus Grace in view of Marx and further in view of Ding et al. does not establish a *prima facie* case of obviousness, as set forth in MPEP §2142. Therefore, claim 38 is also patentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020).

Claims 19-20, 26, 28-30, 32, 33, and 41 are dependent from claims 18 and 38, and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that their rejections are moot in view of the remarks made in connection with independent claims 18 and 38. The dependent claims include all of the limitation of the base claim and any intervening claims, and recite additional features which further distinguish the claims from the cited references. Therefore, claims 19-20, 26, 28-30, 32, 33, and 41 are also patentable under 35 U.S.C. 103(a) over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020):

Applicant respectfully requests that the rejection of claims 18-20, 26, 28-30, 32, 33, 38 and 41 over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020) be withdrawn. Reconsideration is respectfully requested.

3. Claims 34-37, 39, 40, 42 and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in view of Ding et al. and further in view of Matthews et al. (2003/0232310). The modified device of Green and Ding et al. discloses a device that shows the limitations as described above; however, Green does not show the composition comprising therapeutic agent of peroxide. Matthews et al. teach a device comprising a liquid oral therapeutic dental composition comprising therapeutic agent of hydrogen peroxide or carbamide peroxide [0020]-[0022]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Green to have the composition of Matthews et al. in order to whiten or bleach one or more teeth. Matthews et al. teach having instructions in order to show how to use the composition.

Applicant respectfully traverses the rejection.

As noted above, claims 18 and 38 are patentable over Green in view of Ding et al. Likewise, claim 42 is also patentable over Green in view of Ding et al., for at least the same reasons as noted for claim 38. Applicant also agrees with the Examiner that Green does not show the composition, etc.

Matthews et al. discloses a wand for applying a whitening composition to one or more tooth. See paragraph [0003]. "(T)he invention involves the further step of applying the whitening composition to the wand applicator 10. This step may be achieved by bringing the wand applicator 10 into contact with the whitening composition, for instance by dipping the stem member 30 of the wand applicator 10 into the whitening composition." See paragraph [0017]. (Emphasis added). Paragraphs [0020]-[0022] teach that a "relatively sticky material may be included in the whitening composition to thicken the composition and act as a tackifying agent. This sticky material may be a

polymer and may be selected from the group of carbomers known to resist degradation in the presence of peroxides and/or other whitening agents. Suitable carbomers are those that are safe for oral use and will not significantly inhibit whitening. Carbomers generally include acrylic acid backbones and small amounts of polyalkenyl polyether crosslinking agents. A suitable material is carboxypolymethylene.

Carboxypolymethylene can be used to form a glue-like dental whitening composition that itself can act as an adhesive such that the composition tends to remain against a person's teeth. This tackifying agent may be present in an amount from about 0.5 to about 3 weight percent." See paragraph [0021]. "Carboxypolymethylene includes vinyl polymers having active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename CARBOPOL. Carboxypolymethylene is also generally known as carbomer. Different embodiments of the invention may utilize a variety of forms of salts of carboxypolymethylene including complete salts (where all of the acid groups have been neutralized) or partial salts (where only a portion of the acid groups have been neutralized). Further, certain embodiments of the invention may use mixtures of complete and partial salts."

Contrary to the Examiner's contention, Matthews et al do not teach or motivate a moisture or temperature sensitive composition. Even given the more generous interpretation, Matthews et al disclose a dipping method for a whitening composition that is tacky and the use of a tackifying agent to make a tacky composition sticky, like an adhesive, and a dipping method is needed to dispense it. See paragraphs [0017]-[0022]. Neither a dispenser nor a composition of the present invention is disclosed or taught anywhere. In fact, Matthews et al.'s tacky composition and dipping method completely teach away from the present invention. In paragraph [0023], Matthews et al.

disclose that to increase viscosity and resist dilution by saliva, the level of carboxypolymehtylene used needs to be adjusted, signaling that exposure to moist environment can decrease and not increase the viscosity of the composition of Matthews et al. (Emphasis added). Therefore, the deficiencies in Green in view of Ding et al. are not provided by Matthews et al., as the composition of Matthew et al. does not increase in viscosity in a moist environment. Thus, claims 18, 38, and 42 are patentable under 35 U.S.C. 103(a) over Green in view of Ding et al. and further in view of Matthews et al. (2003/0232310).

Claims 34-37, 39, 40, and 51- 58 are dependent from claim 18, 38, and 42, respectively, and are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in view of Ding and further in view of Matthews et al. (2003/0232310). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that their rejections are moot in view of the remarks made in connection with independent claims 18, 38, and 42. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish the claims from the cited references. Therefore, claims 34-37, 39, 40, 42, and 51-58 are also patentable under 35 U.S.C. 103(a) over Green in view of Ding et al. and further in view of Matthews et al. for at least the same reasons as discussed above.

Applicant respectfully requests that the rejection of claims 34-37, 39, 40, 42, and 51-58 under § 103(a) as being unpatentable over Green in view of Ding et al. and further in view of Matthews et al. be withdrawn. Reconsideration is respectfully requested.

4. Claims 34-37, 39, 40, 42 and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of

Matthews et al. The modified device discloses a device that shows the limitations as described above; however, they do not show the composition comprising peroxide. Matthews et al. teach a device comprising a liquid oral therapeutic dental composition comprising therapeutic agent of hydrogen peroxide or carbamide peroxide [0020]-[0022]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device to have the therapeutic agent of Matthews et al. in order to whiten or bleach one or more teeth. Matthews et al. teach having instructions in order to show to use the composition.

Applicant respectfully traverses the rejection.

As noted above, claim 18 is patentable over Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020). Claims 38 and 42 are likewise also patentable over Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020) for at least the same reasons as noted for claim 38.

As also noted above, Matthews et al.'s tacky composition and dipping method completely teach away from the present invention. In paragraph [0023], Matthews et al. disclose that to increase viscosity and resist dilution by saliva, the level of carboxypolymehtylene used needs to be adjusted, signaling that exposure to moist environment can decrease and not increase the viscosity of the composition of Matthews et al. Therefore, the deficiencies in Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020) are not provided by Matthews et al., Otherwise, there will be no need to worry about dilution by saliva. Thus, claims 18, 38, and 42 are patentable under 35 U.S.C. 103(a) over Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020), further in view of Matthews et al. (2003/0232310).

Claims 34-37, 39, 40, 42, and 51-58 are dependent from claims 18, 38, and 42 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Matthews et al. Applicant respectfully submits that as they are dependent from claims 18, 38, and 42, they are also patentable for at least the same reasons as noted for claims 18, 38, and 42 above. Reconsideration is respectfully requested.

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Dragan (6,929,475). The modified device discloses a device that shows the limitations as described above; however, they do not show plurality of bristles aligned generally parallel with lengthwise direction of the device. Dragan teaches a dental device comprising an applicator with plurality of bristles 246 aligned generally parallel with lengthwise direction of the device the composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device to have the applicator of Dragan in order to apply material between teeth and to gum at base of the teeth in view of Dragan.

Applicant respectfully traversed the rejection.

As noted above, claim 18 is patentable over Grace in view of Marx and Ding et al. Dragan et al. teach an applicator pre-dosed with a material, such as a chemical or a medicament. The material is placed on an absorbent portion of the applicator and permitted to dry. The material is then in an inactive, stable state on the applicator, and is re-activated upon being exposed to water, saliva, liquids, or other activating materials, See Col. 1, Line 35-42. Thus, Dragan et al do not teach a liquid oral

therapeutic dental composition, said therapeutic dental composition comprises a moisture or temperature responsive composition that increases in viscosity in a more humid environment (Emphasis added). On the other hand, Dragan's disclosure of using liquid to get a material out of a dry state is completely teaching away from the present invention, since going from a dry state to a wet state involves a decrease, not an increase, in viscosity. Thus, the deficiencies in Grace in view of Marx and Ding et al. are not supplied by Dragan, for the reasons noted above. Therefore, claim 18 is also patentable over Grace in view of Marx and Ding et al., and further in view of Dragan.

Claim 31 is dependent from claim 18 and is rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Dragan (6,929,475). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that their rejections are moot in view of the remarks made in connection with independent claim 18. The dependent claim includes all of the limitations of the base claim and any intervening claims, and recites additional features which further distinguish the claim from the cited references. Therefore, claim 31 is also patentable under 35 U.S.C. 103(a) over Grace in view of Marx and Ding et al. and further in view of Dragan.

Applicant respectfully requests that the rejection of claim 31 under § 103(a) as being unpatentable over Grace in view of Marx and Ding et al. in further view of Dragan be withdrawn. Reconsideration is respectfully requested.

IV. Drawings

The Examiner objected to the drawings under 37 CFR 1.83(a). New figure 9 is objected to for containing boundary of reservoir and piston not disclosed in the specification. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figures of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant respectfully traverses the objections.

As noted above, the piston and reservoir are disclosed in the specification. See for example, Paragraphs [0051], [0053] and [0055], listed below:

"[0051]The inventive compositions are preferably disposed in a delivery device 10 (e.g., FIGS. 2-4), such as a dispensing tube, pencil, pen or liquid stick having an applicator 12, such as a felt tip 14 (FIG. 3), brush 16 (FIG. 4), roller ball 17 (FIG. 11), or

non-woven pad. In one embodiment, the delivery device 10 includes more than one applicator 12 that may be removably engaged with the device 10. In an embodiment wherein the device 10 is a pen or a pencil, the applicator 12 may be retractable and/or housed in a cap 18. The therapeutic dental composition L of the present invention may be housed directly within a reservoir 20 in the device 10 or may be supplied in a removable cartridge (not shown) within the reservoir 20 that may be replaced or refilled. The delivery device 10 may dispense the therapeutic dental composition through a transfer channel 21 through capillary action, such as in a flow through pen, or through an activator 22, such as mechanical piston 23 with a click mechanism 25, as shown in FIG. 9, twist button and ratchet mechanism 27, as shown in FIG. 10, or push button mechanism, or through a vacuum method of ejection, or through other such mechanical means for transferring the composition from the device to an oral cavity surface in need of treatment. The activator 22 may be present on first end 24 of the device 10 and the applicator on a second end 26 of the device 10 or the activator 22 may be present on a side wall 28 of the device. In one embodiment, the delivery device 10 includes a felt tip 14 or brush 16 applicator 12 wherein the inventive composition is dispensed to the applicator 12 through actuation of the activator 22, such as by a clicking 25 or twisting mechanism 27. Kotobukie Company, Japan, is one manufacturer of such types of delivery devices 10.

[0053] Upon applying external pressure to the activator 22 to expel the composition from the reservoir 20, the dental composition responds to shear forces introduced by the external pressure, and is temporarily reduced in viscosity to allow for ease of movement of the composition from the reservoir 20 through the transfer channel 21 to the applicator 12. Once the composition is positioned on the applicator 12, the user

applies the composition to the teeth or gum surfaces, using the applicator 12 to apply and distribute the composition on the teeth and/or gums. Optionally, a set of instructions may be provided to the user in order that a particular application method or protocol be employed to apply the composition from the device 10 onto the teeth and/or gums in order to optimize the performance of the composition. With a twist mechanism 27, the user twists the activator 22 on the first end 24 of the delivery device 10 and the therapeutic dental composition L travels from the reservoir 20 through the transfer channel 21 to the applicator 12 at the other end. With the push button activator 22, the therapeutic dental composition L is delivered to the oral cavity surface with the push of a button activator 22 on the first end 24 or side wall 28, which transfers the composition from the reservoir 20 through the transfer channel 21 to the applicator 12.

[0055] The dental gel composition can be dispensed from any suitable delivery device 10 as described above. For example, the dental composition may be dispensed as a liquid or thin gel from a push button (FIG. 9) or twist actuated (FIG. 10) pen with an advancing piston mechanism 23 that expels a predetermined amount of liquid or gel through an orifice. The pen delivery device 10 just described may also optionally comprise a set of bristles, advantageously positioned near or around the orifice through which the therapeutic dental liquid or gel is expelled. Expelling the therapeutic liquid or gel through the orifice and onto said bristles, the user may apply the therapeutic composition directly onto the teeth, thereby forming a thickened gel upon application. Alternatively, the dental composition may be brushed onto an oral cavity surface, using a brush (FIG. 4) or felt tip (FIG. 3) that is replenished with the therapeutic composition by returning it to a reservoir containing said composition or by clicking or twisting a dispensing portion of the reservoir. Yet another mode of application is placement of the

inventive therapeutic liquid or gel composition into a dental tray, whereupon the dental tray is inserted into place around a patient's teeth. Plastic strips may also be coated with a predetermined dose of the therapeutic responsive dental gel and placed against the teeth or gums of a subject. Alternatively, the inventive compositions may be applied by placing an amount on a swab or other such device, and simply applying directly to the intended oral cavity surface."

While it is true that the cross-section of the dispenser was not clearly shown as originally filed, the components of the dispenser, however, were sufficiently described, as noted in the above paragraphs. Specifically, "A therapeutic dental composition L of the present invention may be housed directly within a reservoir 20 in the device 10 or may be supplied in a removable cartridge (not shown) within the reservoir 20 that may be replaced or refilled." See paragraph [0051]. Thus, the reservoir is clearly bounded inside the dispenser. Applicant respectfully submits that this disclosure alone sufficiently discloses a boundary for the reservoir. However, the disclosure does not stop here, in paragraph [0053], the specification goes on to describe "ease of movement of the composition from the reservoir 20 through the transfer channel 21 to the applicator 12", "The delivery device 10 may dispense the therapeutic dental composition through a transfer channel 21 through capillary action, such as in a flow through pen, or through an activator 22, such as mechanical piston 23 with a click mechanism 25, as shown in FIG. 9, twist button and ratchet mechanism." Applicant respectfully submits that the location of both the piston and reservoir are sufficiently disclosed in the paragraphs listed above. As for the boundaries of the piston and reservoir, Applicant respectfully submits that a piston and a reservoir, by definition have physical forms and as such, have boundaries. No new matter has been added.

However, in the interest of advancing prosecution, Applicant has presented the piston with dotted lines. See replacement page Sheet 6 of 6. Favorable action is respectfully requested.

V. CONCLUSION

In view of the amendments and remarks set forth above, Applicant respectfully submits that the application is in condition for allowance and early notice thereof is respectfully solicited.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8501.

Dated: January 25, 2008

Respectfully submitted,



Nancy N. Quan

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